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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,176	06/09/2005	Chikamasa Yama	04676.0184-00000	1747

22852 7590 10/04/2007  
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901 NEW YORK AVENUE, NW  
WASHINGTON, DC 20001-4413

EXAMINER
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ALI, SHUMAYA B

ART UNIT	PAPER NUMBER
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3771

MAIL DATE	DELIVERY MODE
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10/04/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/538,176

Applicant(s)

YAMA ET AL.

Examiner

Shumaya B. Ali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10 and 11 is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Status of Claims*

In response to the office action mailed on 4/9/07, Applicant has amended claims 2 and 4. Currently claims 1-11 are pending in the instant application.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. US 5,785,049 in view of Sladek US 6,039,042.**

As to claims 1 and 4, Smith discloses (see figs 1 and 2) an inhalation device for transpulmonary administration comprising: a chamber (12) for containing a pharmaceutical composition which is pulverized into fine particles by an air-generated impact for dispersal in

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air; an air inlet flow path (44) for introducing to the chamber outside air to apply the air-generated impact to the pharmaceutical composition and for injecting the outside air toward the pharmaceutical composition; an inhalation flow path (46) having a suction port (a port at the open end of 46 in fluid communication with the chamber 12) located inside the chamber to inhale the pulverized pharmaceutical composition; a housing (11) for accommodating the chamber, the air inlet flow path, and the inhalation flow path; a mouthpiece (32) provided at one end of the housing, the mouthpiece being provided with a mouth-side flow path (air channel though mouthpiece 32) which communicates with the inhalation flow path. Smith however lacks an auxiliary flow path. However, Sladek teaches a mouthpiece with an auxiliary flow path (fig.6, path through 24). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Smith in order to provide an auxiliary flow path because it is known in the art as taught by Sladek. Smith further discloses the inhalation device for transpulmonary administration is configured such that the air-generated impact is applied to the pharmaceutical composition by the outside air which flows into the chamber by inhalation-induced pressure generated when a user (patient) inhales air, and the pulverized pharmaceutical (col.11, lines 34-56).

**As to claims 2 and 6**, Sladek teaches a divider (fig.6, 16) having an orifice (fig.6, 17).

**As to claim 3**, Sladek teaches a plurality of dividers (fig.6, 16s).

**As to claim 5**, Sladek teaches an air outlet (fig.6, opening though 24) which opens into the mouth side flow path.

**As to claim 7**, Sladek teaches a flow path length of the orifice is formed to be elongated to the air discharge direction of the mouth-side flow path (see fig 6).

**Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. US 5,785,049 and Sladek US 6,039,042 and in view of Praud US 5,497,765.**

As to claim 9, Smith lacks a check valve. However Praud teaches an inhaler with a check valve (fig. 1, 23). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Smith in order to provide a check valve because it is known in the art as taught by Praud.

***Allowable Subject Matter***

Claim 8 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 10 and 11 are allowable over the prior art of record.

***Response to Arguments***

Applicant's arguments with respect to claim 1-11 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-W-F 8:30am-5:00 pm.

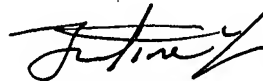
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Shumaya B. Ali  
Examiner  
Art Unit 3771



JUSTINE R. YU  
SUPERVISORY PATENT EXAMINER  
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10/1/07